K121709

Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
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510k No.:

OCT 19 2012

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Cecilia Silva

Date Prepared: October 18, 2012

2. Device Name:

Trade Name:	Zfx Dental CAD System
Regulation Number:	872.3630 / 872.3661
Classification Code:	NHA / NOF
Device Classification Name:	Endosseous Dental Implant Abutment / Optical Impression Systems for CAD/CAM

3. Predicate Device(s):

Trade Name:	etkon™_visual, etkon™ es1, Straumann CARES
Regulation Number:	872.3630 / 872.3661
Classification Code:	NHA / NOF
Device Classification Name:	Endosseous Dental Implant Abutment / Optical Impression Systems for CAD/CAM

4. Device Description:

The Zfx Dental CAD system is software that is used to design dental restorative prosthetic devices from digital optical impressions. The software receives topographical characteristics of dental impressions or stone models from a compatible scanning system. The design created in the software is complied into a format enabling manufacturing of a patient specific component at Zimmer Dental. The CAD software is pre-installed on a Windows compatible computer system.

5. Indications for Use:

The Zfx Dental CAD System is intended to allow the user to acquire patient specific data via a scan or digital file and define the shapes of dental prosthetic devices such as dental abutments, crowns, bridges, copings, in-lays, on-lays, and veneers through the use of a 3D-CAD tool. Zfx Dental CAD System creates an output file of the restorations designed by the user that can be manufactured using a CAM system.

6. Device Comparison:

The new device is substantially equivalent to the predicate relative to the software that allows a digital design of patient specific ("customized") abutments, crown, bridge, and components, and the operating software that controls a scanner. The function and intended use of the dental CAD system remains equivalent to the predicate device.

7. Technological Characteristics

Feature/ Components	**New Device** *Zfx Dental CAD System*	**Predicate** *etkon™es1* *etkon™_visual* *Straumann CARES*
Indication	The Zfx Dental CAD System is intended to allow the user to acquire patient specific data via a scan or digital file and define the shapes of dental prosthetic devices such as dental abutments, crowns, bridges, copings, in-lays, on-lays, and veneers through the use of a 3D-CAD tool. Zfx Dental CAD System creates an output file of the restorations designed by the user that can be manufactured using a CAM system.	etkon_visual is a software device intended to import patient-specific data from a scanner for CAD (computer aided design) design of individual dental restorations like crowns, bridges, inlays, onlays, veneers and abutments. etkon_visual also facilitates the transfer of 3D data from a dental lab to a remote milling center by internet connection and serves as an order management tool.
Input	STL file from a scanner	STL file from a scanner
Design Options	Dental prosthetic devices: Abutments, crowns, bridges, copings, in-lays, on-lays and veneers.	Individual Dental Restorations: Crowns, bridges, inlays, onlays, veneers and abutments.
Output	STL file to a Zimmer Dental milling center	STL file to a Straumann CAD/CAM milling center
PC/Monitor	Provided as part of the System	Provided as part of the System
Network Cables	Provided as part of the System	Provided as part of the System
GUI/OS	Windows®7 64 bit Operating System	Windows®7 64 bit Operating System

8. Non-Clinical Testing:

a) Verification and Validation Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005).

Verification and validation testing of the Zfx Dental CAD system has been completed. Validation testing has been conducted to demonstrate that the Zfx Dental CAD system can accept a digital scan file from a compatible dental scanner, and design a patient specific restoration, such as an abutment, crown, or bridge. Verification testing has been conducted to verify that a patient specific restoration can be manufactured by Zimmer to the required design specifications.

9. Clinical Testing

No clinical testing was performed.

10. Conclusion

Based on our analysis, the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Zimmer Dental, Incorporated
Ms. Cecilia Silva
Regulatory Affairs
1900 Aston Avenue
Carlsbad, California 92008

Re: K121709
Trade/Device Name: Zfx Dental CAD System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, NOF
Dated: September 17, 2012
Received: September 18, 2012

Dear Ms. Silva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121709

zimmer dental

Indications for Use

510(k) Number (if known): K121709

Device Name: ***Zfx Dental CAD System***

Indications For Use:

The Zfx Dental CAD System is intended to allow the user to acquire patient specific data via a scan or digital file and define the shapes of dental prosthetic devices such as dental abutments, crowns, bridges, copings, in-lays, on-lays, and veneers through the use of a 3D-CAD tool. Zfx Dental CAD System creates an output file of the restorations designed by the user that can be manufactured using a CAM system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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